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Risedronate for the prevention of bone loss after steroid therapy for a flare-up in inflammatory bowel disease

Submission date 16/11/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/11/2008	**Overall study status** Completed	
Last Edited 06/10/2011	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jonathan H Tobias

Contact details
Academic Rheumatology
Avon Orthopaedic Centre
Southmead Hospital
Bristol
United Kingdom
BS10 5NB

Additional identifiers

EudraCT/CTIS number
2004-004325-10

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ME/2005/2018; 2004-004325-10

Study information

Scientific Title
A randomised controlled trial to evaluate whether a short course of once weekly risedronate prevents bone loss following high-dose steroid therapy for an acute exacerbation of inflammatory bowel disease

Study objectives
The hypothesis is based on the observation that osteoporosis occurs in patients with inflammatory bowel disease (IBD) and that detectable bone loss occurs after steroid treatment for only 8 weeks. Bisphosphonates are effective at treating bone loss but whether it is effective at preventing bone loss in this context is being addressed in this trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gloucestershire Research Ethics Committee approved the trial in June 2005 (ref: 05/Q2005/74)

Study design
Radonmised, double-blind, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Inflammatory bowel disease (ulcerative colitis and Crohn's disease)

Interventions
All patients participating in the trial were given calcium and vitamin in the form of Cacit D3 effervescent granules (calcium 500 mg/Vitamin D 440IU) at a dose of one sachet daily. Patients were randomised to risedronate 35 mg weekly or a placebo.

The total duration of intervention was 8 weeks and follow up was for the same 8 weeks in both arms. Participants were seen at baseline and then 8 weeks.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Risedronate

Primary outcome measure
The difference in percentage change in total hip (and sub-regions of the hip) and lumbar spine bone mineral density (BMD) measured by dual x-ray absorptiometry (DXA) 8 weeks apart between treatment groups (baseline is when corticosteroids start and week 8 at completion of the steroids).

Secondary outcome measures
1. Do patients with ulcerative colitis and Crohn's disease have a differential response to steroid therapy or risedronate?
2. Change in markers of bone turnover (CTX for resorption and P1NP for formation) measured before steroids start (week -1), baseline and at week 8
3. Urinary steroid metabolites and cytokines measured from samples obtained at week -1

Overall study start date
01/10/2005

Completion date
30/09/2007

Eligibility

Key inclusion criteria
1. Aged greater than or equal to 16 years, either sex
2. Ulcerative colitis and Crohn's disease
3. Experiencing a relapse
4. Requiring steroid therapy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Aged under 16 years
2. Use of corticosteroids in the preceding 3 months
3. Evidence of osteoporosis (known vertebral fracture, T score less than -2.5)
4. Pregnant and lactating women

5. Women of childbearing age will be eligible provided they use reliable contraception
6. Bone active therapy within previous 12 months (excluding calcium and low dose vitamin D)
7. Previous treatment with a bisphosphonate at any time
8. Associated disorder which may influence bone metabolism
9. Lactose intolerance

Date of first enrolment
01/10/2005

Date of final enrolment
30/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Rheumatology
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details
c/o Dr Maria Palmer
Director of Research and Effectiveness Department
Bristol Royal Infirmary
Bristol
England
United Kingdom
BS2 8HW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble Pharmaceuticals (UK) - educational grant.

Funder Name
The funder had no input into the study design, recruitment or the analysis of the results.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2010		Yes	No